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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,104	03/16/2001	Fernando J. Isaza	PURIT 54796	8305

24201 7590 05/22/2003

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EXAMINER

LEWIS, AARON J

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 05/22/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,104

Applicant(s)

ISAZA ET AL.

Examiner

AARON J. LEWIS

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,9,17-21 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 and 5 is/are allowed.
- 6) ☒ Claim(s) 1,2,4,9,17-21 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Reissue Applications

1. The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

1. Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,881,717 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

2. The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

The oath or declaration does not state that the person(s) making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person(s) to be material to patentability as defined in 37CFR 1.56; rather, the declaration incorrectly acknowledges a duty to disclose all information material to examination of the application. A new oath or declaration in compliance with 37CFR 1.63, 1.67 and 1.175 is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1,2,4,9,17-21,25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jonsson et al.('208) in view of Dahl ('357).

As to claim 1, Jonsson et al. (col.3, lines 21-42) disclose a method for detecting the status of connections of a patient tubing system of a pneumatically driven, electrically controlled ventilator system used to provide breathing gas to a patient, the method including a plurality of control intervals during both inhalation and exhalation, comprising the steps of: determining an onset of an exhalation phase of a patient's breath cycle (col.6, lines 18-20); monitoring exhalation flow and pressure in the patient tubing system (col.3, lines 31-34) during a plurality of control intervals of said exhalation phase of the breath cycle to determine whether a condition indicating disconnection of the patient tubing system has occurred; generating a signal (col.3, lines 40-42) indicating disconnection of the patient tubing system if said condition indicating disconnection of the patient tubing system has occurred.

The difference between Jonsson et al. and claim 1 is the express recitation of an alarm signal being a "disconnection signal".

Dahl, in a method and apparatus for detecting disconnection of a patient tubing system, teaches the generation of a disconnection signal responsive to detection of a pressure loss in the patient tubing (col.1, lines 51-58).

Inasmuch as Jonsson et al. disclose the monitoring of pressure within the patient tubing for the express purpose of determining operational status of the ventilator including any leakage from the connections, it would have been obvious to one of ordinary skill that leakage from patient tubing connections as detected by Jonsson et al. include leakage from the patient tubing resulting from a disconnection as taught by Dahl.

As to claim 2, the patient tubing system of Jonsson et al. includes an exhalation line (fig.3, note exhalation flow through flow meter 12), and said step of monitoring exhalation flow and pressure in the patient tubing system comprises sensing pressure (24) and flow (12) in said exhalation line, and declaring disconnection (col.3, lines 40-42) of the patient tubing system has occurred if, during a control interval, the pressure in the exhalation line is within a predetermined pressure range, and if exhalation flow is less than a predetermined flow threshold, for a contiguous period of consecutive control intervals (col.6, lines 18-24) with a predetermined initial period of time following onset of an exhalation phase.

As to claim 9, Jonsson et al. disclose the control intervals to have a predetermined duration (col.6, lines 18-24).

As to claim 4, Jonsson et al. as discussed above also deliver a flow of breathing gas to a patient during an inspiratory phase of a breath cycle (2); monitors a desired flow

target of breathing gas (6,8) and declares disconnection of the patient tubing system has occurred if the desired target flow is greater than or equal to a maximum flow threshold, and the duration of a current inspiration is greater or equal to a maximum allowed spontaneous inspiration time (col.6, lines 52-57).

Claims 17 and 18 are substantially equivalent in scope to claims 1 and 2 respectively, and are included in Jonsson et al. as modified by Dahl for the reasons set forth above with respect to claims 1 and 2.

As to claim 25, Jonsson et al. disclose the control intervals to have a predetermined duration (col.6, lines 18-24).

As to claim 19, Jonsson et al. as modified by Dahl as discussed above, also teach a pressure sensor (24) connected to the exhalation line and a flow sensor (12) connected to the exhalation line. The recited contiguous period of consecutive control periods is readable upon the time period of detection during exhalation as defined in Jonsson et al. at col.6, lines 18-24).

Claim 20 is substantially equivalent in scope to claim 4 and is included in Jonsson et al. as modified by Dahl for the reasons set forth above with respect to claim 4.

Claim 21 is substantially equivalent in scope to claim 5; however, the recited "...means for declaring..." is readable upon elements 4 and 5 of Jonsson et al. and is included in Jonsson et al. as modified by Dahl inasmuch as the expiration servo unit 4 and monitoring unit 5 of Jonsson et al. are fully capable of performing the recited function of determining exhalation flow with respect to time, multiplied by a proportional factor and a disconnection sensitivity factor for three consecutive breaths.

Allowable Subject Matter

5. Claims 3 and 5 are allowed.

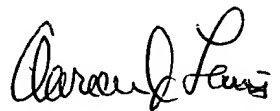
Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant methods and devices for determining patient tubing disconnection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (703) 308-0716. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, WEILUN LO can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


AARON J. LEWIS
Primary Examiner
Art Unit 3761

Aaron J. Lewis
May 17, 2003